View metadata, citation and similar papers at core.ac.uk

brought to you by CORE

provided by Institutional Knowledge at Singapore Management University

Singapore Management University

Institutional Knowledge at Singapore Management University

Research Collection School of Social Sciences | School of Social Sciences

1-2016

Achieving regulatory excellence in the agri-food biotechnology sector: Building policy capacity

Michael HOWLETT

Ishani MUKHERJEE

Singapore Management University, ishanim@smu.edu.sg

Follow this and additional works at: https://ink.library.smu.edu.sg/soss_research

Part of the Agribusiness Commons, and the Public Affairs, Public Policy and Public Administration Commons

Citation

HOWLETT, Michael, & MUKHERJEE, Ishani.(2016). Achieving regulatory excellence in the agri-food biotechnology sector: Building policy capacity. *Asian Biotechnology and Development Review, 18(1)*, 35-46.

Available at: https://ink.library.smu.edu.sg/soss_research/2514

This Journal Article is brought to you for free and open access by the School of Social Sciences at Institutional Knowledge at Singapore Management University. It has been accepted for inclusion in Research Collection School of Social Sciences by an authorized administrator of Institutional Knowledge at Singapore Management University. For more information, please email libIR@smu.edu.sg.

RIS
Research and Information System
for Developing Countries

Asian Biotechnology and Development Review
Vol. 18 No. 1, pp 35-46
© 2016, RIS.

Achieving Regulatory Excellence in the Agri-Food Biotechnology Sector: Building Policy Capacity

Michael Howlett
Ishani Mukherjee

Abstract: What capacities are needed on the part of policymakers in areas such as the agri-food biotechnology sector in order to attain excellence at the individual, organisational and systemic levels of regulatory operation? To address this question, this paper draws upon work recently carried out on regulatory excellence by the Penn Programme on Regulation and couples it with recent studies on how to build policy capacity. Derived from a multi-jurisdiction, multi-sector review of regulation, the Penn programme identified three core areas or 'pillars' of regulatory excellence – namely, stellar competence, empathic engagement and utmost integrity –which reflect the kinds of individual actions of a regulator, the traits of the regulator as an organisation, and the broad systemic outcomes of regulation which are needed for excellent performance. This work does not examine what is needed on the part of public organisations to achieve these goals, however, and to this end, the paper draws upon a second set of recent studies into the various types of policy capacities that affect policy-making to illustrate what regulators must do in order to achieve excellence. Examples from agri-food biotechnology regulation are used to illustrate the concepts of, and prerequisites for, achieving regulatory capacity and excellence in this sector, although the lessons and implications are also valid in many others.

Keywords: regulatory capacity, precautionary principle, regulatory excellence, integrity, engagement

Introduction: The Concept of Regulatory Excellence

Questions regarding how to improve regulatory processes and bring about better outcomes of regulations have occupied the attention of many academics and regulatory practitioners over the last three decades (Hood

* Burnaby Mountain Professor Department of Political Science, Simon Fraser University, Burnaby BC Canada and Yong Pung How Chair Professor, Lee Kuan Yew School of Public Policy, National University of Singapore, Singapore. E-mail: howlett@sfu.ca (Corresponding author)

** Postdoctoral Fellow, Lee Kuan Yew School of Public Policy, National University of Singapore, Singapore. E-mail: sppim@nus.edu.sg

1995; Graham 2005; Coglianese and Nash 2006; Moynihan 2008; Finkel *et al.* 2015). Regulatory 'best practices' identified in these studies have included suggestions for enhancing participation in the formulation process of regulations (Ansell and Gash 2007); applying standard and transparent performance and progress management mechanisms for attaining public value (Moynihan 2008; Radin 2009), and engaging strategically with stakeholders in the regulated industry or activity (Hutter 1997). These indicators of regulatory excellence echo those identified by national and multilateral agencies alike (World Bank 2006; UK Environment Agency 2013; Gardener *et al.* 2013).

Recently a systematic analysis of regulatory strategic plans from around the world, including Canada and the United States, examined many instances of regulatory activity in order to identify the structure and behaviour needed to achieve exceptional performance. Like those identified earlier, these related to analytical know-how, instrumental aptitude and high standards of performance; purposeful, even-handed engagement with stakeholders and civil society members; and the attainment of the highest level of integrity among regulators with respect to fidelity to the law, commitment to the public interest and dedication to democratic principles and practices (Coglianese 2015). This multi-jurisdiction, multi-sector review of regulation, identified three core 'pillars' of regulatory excellence behind these practices: *stellar competence, empathic engagement* and *utmost integrity,* each of which can be reflected in the individual actions of a regulator, the traits of the regulator as an organisation, and the broad systemic outcomes of regulation related to public value (Coglianese 2015).

While clear in its explanation of what defines regulatory excellence, however, the Penn work and those others cited above do not examine in detail what is needed on the part of public organisations to achieve these goals. That is, what capacities, competences and capabilities at individual, organisational and systemic levels of regulatory operation are needed on the part of policymakers to attain regulatory excellence?

To address this question, this paper draws on ongoing research work on policy capacity in the field of public policy (Wu *et al.* 2015) and couples the insights of this work to the synthesis on regulatory excellence established bythe Penn Programme. The findings from this work are illustrated and

applied to the agri-food biotechnology sector although many of these conclusions and insights apply to many other policy sectors as well.

Policy Capacity at the Individual, Organisational and Systemic Levels

Adopting a multi-level perspective on the capacities needed for regulatory excellence is necessary in order to analyse exactly how and at what levels of regulatory activities distinction can be achieved.

Studies of the formulation and implementation of policy in general have concluded that success in these activities rests on the interplay of analytical, managerial and political capacities on the part of individual policy actors, regulatory organisations and the general policy system (Wu *et al.* 2015; Gleeson *et al.* 2011). These policy capacities span a variety of analytical resources that are needed to help effectively generate policies, including regulations, and also include the managerial capabilities that let state resources be allocated effectively to different policy priorities and the political endowments that delineate the policy making space that policymakers and administrators have to coordinate, create and implement their plans (Tiernan and Wanna 2006; Gleeson *et al.* 2011; Wu *et al.* 2010; Rotberg 2014; Howlett and Ramesh 2015).

The combination of resources and skills available at different levels of policymaking yield nine distinguishable types of policy capacity (Table 1).

Table 1: Dimensions and Levels of Policy Capacity

Level Dimension	Individual Level	Organisational Level	System Level
Analytical Skills	**1. Policy Analytical Capacity** Knowledge of policy substance and analytical techniques and communication skills	**2. Organisational Information Capacities** Information and e-services architecture; budgeting and human resource management systems	**3. Knowledge System Capacity** Institutions and opportunities for knowledge generation, mobilisation, and use

Table 1 continued...

Table 1 continued...

Operational Skills	**4. Managerial Expertise Capacity** Leadership; strategic management; negotiation and conflict resolution	**5. Administrative Resource Capacity** Funding; staffing; levels of intra-agency and inter-agency coordination	**6. Accountability and Responsibility System Capacity** Rule of law; transparent adjudicative system
Political Skills	**7. Political Acumen Capacity** Understanding of the needs and positions of different stakeholders; Judgment of political feasibility	**8. Organisational Political Capacity** Politicians' support for the agency; levels of inter-organisational trust and communication	**9. Political economic system capacity** Public legitimacy and trust; adequate fiscal resources

Source: Howlett and Ramesh (2015).

At the individual level, analytical capacity entails various substantive skills, while managerial capacities surround effective individual leadership and management strategies, and political competences are embodied by the individual acumen of regulatory actors to assess the needs and interests of different stakeholders. For organisations, pertinent analytical skills are centred on information dissemination and creating an information sharing architecture for the effective transfer of knowledge within and across administrative agencies, while managerial competences surround successful coordination of resources and staffing between agencies, and political aptitude has to do with gaining political support and trust for the agency and its efforts. At the systemic level the wealth of a society, the extent of accountability of its administrative system and the quality of its knowledge system are all key components, and indicators, of policy capacity.

Each of the Penn Programme pillars of regulatory excellence set out above can be seen to draw on each of these capacities. Excellence requires informed individual regulator actions, organisational-level agency traits which promote evidence-based and technical competences and system level traits which confer legitimacy or governments and their actions.

Coupling each of the nine indicators of capacity with the tenets of excellence identified by the Penn programme results in the situation set out in Table 2. That is, each of the principle 'tenets' of regulatory excellence set out in the Penn programme can be seen to require high levels of capacity in terms

of individual level efficiency, education and information; multiplicative agency relationships, proportionality of regulatory response to perceived public risks, and agency vitality based on skill and resource endowments, as well as equity in the distribution of regulatory cost, benefits and public engagement; honesty and the upholding of regulatory integrity (Finkel et al. 2015; Coglianese 2015).

Table 2: Capacity Requisites of Regulatory Excellence

Level of Regulatory Excellence **Core Regulatory Qualities and Defining Capacities**	**Individual Actions**	**Organisational-level traits**	**Systemic Outcomes**
Analytical Capacity **Stellar Competence**	**Analytical Know-How** • Scoping of data reliability and synthesis of quality evidence • Technically consistent analysis • Smart management of risks	**Instrumental Aptitude** • Sufficiently funded and highly trained staff • Organisational culture supportive of adopting high quality, innovative tools and technologies • Regular performance evaluation and management	**High Performance Standards** • Consistent and quality delivery of public value
Managerial Capacity **Emphatic Engagement**	**Even handedness** • Fair and egalitarian engagement with regulation targets • Outreach to ensure participation and equal opportunity to communicate interests	**Attentiveness** • Awareness of regulator and policy target interests and incentives	**Responsiveness** • Timely engagement and response to concerns • Providing full and open explanations of regulatory decisions and decision making processes

Table 1 continued...

Table 1 continued...

Political Capacity **Utmost Integrity**	**Fidelity to Law** • Regulator compliance with all laws and legal procedures	**Commitment to public interest** • Primary and unbiased focus of regulatory body to serve public interests	**Upholding democracy** • Clear delineation of responsibilities of elected officials, administrators and regulators. • Initiating and contributing to public dialogue on policy issues relevant to regulatory action.

The Agri-Food Case

These basic principles and the need for high levels of policy capacity in order to achieve regulatory excellence are well illustrated by the agri-food biotechnology case. In this rapidly progressing field of regulation, several questions regarding lessons for the achievement of excellent policy and governance outcomes and processes have been raised and continue to be made as governments balance their support of biotechnology research and trade implications with regulatory oversight and civil society concerns.

Efforts towards the improved regulation of agricultural biotechnology have taken place in a variety of different jurisdictions and through a variety of different policy processes over the last four decades. This regulation has evolved beyond a 'first generation' focus on genetic engineering technologies and the development of genetically modified organisms (GMOs), towards a 'next generation' emphasis on innovations in technologies related to genomics, proteomics, metabolomics and transcriptomics (collectively labelled as 'omics' technologies) and has moved from the realm of scientific expert to the public realm of concern for individual and public health as well as that of crops and agricultural bio-systems in general (Laycock and Howlett 2013).

Aiming for policy effectiveness and striving for excellence in a complex area such as agri-food biotechnology regulation requires sound analytical, operational and political capacities on the part of those tasked with designing and delivering policy. These competences are important across the board even if the organisational structure of agricultural biotechnology regulation may vary by jurisdiction, especially so since most governments are now

"moving to establish flexible biosafety systems on the basis of internationally accepted guidelines and linked to existing national legislation" (Komen and Persley1993, p. 48).

Critical Capacities for Achieving Excellence in Agri-Food Biotechnology Regulation

There is no doubt that all the nine different capacities identified in Table 1 are important for the effective generation of biotechnology regulations in the agri-food sector. That is, in general, at the broadest systemic level, analytical abilities are needed for the creation of institutions and opportunities for knowledge generation, managerial capabilities are needed to design and implement a transparent adjudicative system and systemic capacities are required to uphold the rule of law and gain widespread public legitimacy (Howlett and Ramesh 2015; Woo *et al.* 2015). However, a specific focus on regulatory capacity can go a step beyondthis to define the key or *critical attributes* of the analytical, managerial and political skills and resources that are necessary to achieve regulatory *excellence* (Coglianese 2015; Finkel *et al.* 2015).

Firstly, achieving the exceptional regulatory competence identified in the Penn scheme depends on having the *analytical capacities* needed to develop effective technical knowledge and skills, "risk-informed priority setting" and achieve high performance delivery of intended regulatory outcomes (Coglianese 2015; Finkel *et al.* 2015). At the level of regulatory action, having well-resourced and sound analytical competence and skills leads to the generation of reliable data and the quality evidence which makes available technically consistent analysis to efficiently manage risks. Similarly, having sound instrumental aptitude depends on the establishment and operation of high level organisational information capacities, including budgeting and management systems that allow regulatory organisations to have sufficiently funded and highly trained personnel and an organisational environment that is conducive to innovation and regular performance evaluation. At the systemic level, capacities for knowledge generation, mobilisation and use determine high performance standards for delivering public value through regulation. For example, annual reports such as those made available through the USDA Foreign Agricultural Service (FAS) make available information on field tests conducted on GMO crops, coexistence

laws and monitoring of agronomic performance which is essential for effective regulation.

Secondly, having high level managerial capacities on the part of regulators is essential to engaging effectively with the public as well as with the subjects or targets of regulation. Leadership, strategic management and arbitration skills are necessary to ensure an egalitarian approach to regulation targets, allowing for even-handed opportunities for communicating various public interests. Many European nations with a long history of public debates on the merits and hazards of agricultural biotechnology, for example, have designed a variety of mechanisms for enhancing public participation in the deliberation process which has added to the legitimacy and perceptions of the efficiency and effectiveness of European regulators (Howlett and Laycock 2013). These include a variety of means for stakeholder consultations as well as participatory technological assessments (TA)involving either ordinary citizens or expert representatives in order to bring forward "marginalised alternative problem-definitions that would suggest different evaluation criteria and alternative innovation trajectories", for products such as genetically modified crops in France and the UK, and herbicide-tolerant crops in Germany (Levidow 2007).

At the organisational level, administrative capacities allowing effective inter- and intra-agency communication are vital assessing and designing incentives aimed at policy targets as well as clarifying the regulator's own interests in regulatory activity. For example, the US agricultural biotechnology regulation, as governed by its 1986 Coordinated Framework for Regulation of Biotechnology Products (51 Fed. Reg. 23302), relied, and continues to rely, on the concerted regulatory action of three existing federal agencies – the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) – rather than creating a separate new agency for agricultural biotechnology regulation. This was only possible as it was judged that all the federal departments have "reflected a position that biotechnology could be adequately regulated through the existing federal infrastructure and by adapting existing laws to new technologies" (Belson 2000, p. 268) given their high levels of capacity in this area.

Similarly, at the level of regulatory outcomes, high levels of individual, organizational and systemic capacities for accountability and transparent

adjudicative procedures ensure that regulators are able to engage and respond to concerns in a timely manner while providing full explanations of regulatory decisions and processes. Modern regulatory regimes for agri-food biotechnology in Asian countries such as Japan, Korea and China, for example, have been strongly responsive to civil society and non-governmental groups who have been able to raise concerns on the government agenda to influence the rigorous regulation of genetically modified agricultural products, enhancing the legitimacy of both products and regulators in so doing. All three countries have now adopted mandatory labelling (unlike the US or Canada). And all three have ratified the Cartagena Protocol: Japan in 2002, China in 2005 and Korea in 2008(Tiberghien 2012, p. 125).

Lastly, for a regulator to aspire for utmost integrity in "its commitment to serving the public interest, to respecting the law and duly elected representatives" (Coglianese 2015, p. 23) high level political capacities are needed to realize and garner widespread policy and social support for existing and proposed regulations. At the individual level the political acumen of regulators for "understanding the political trade-offs necessary for an agreement among contending actors and interests" is key (Wu *et al.* 2015, p. 169; Pal and Clarke 2015). Organisational level political capacity, on the other hand, goes beyond individual-level capacities for assessing feasibilities and compliance with laws, to ensure broader inter and intra-agency learning and political support (Dunlop 2015).Exceptional integrity at the organisational level is defined by an unbiased commitment to serving public interests (Coglianese 2015). The European Commission's regulatory regime surrounding biotechnology is strongly embedded in the precautionary principle in direct response to public concerns regarding the possible negative effects of GMOs (European Commission 2000) and is a good example of this. Directive 2001/18 adopted by the Commission in 2001 had an explicit goal to inspire public trust in GMO regulatory processes (Johansson 2013), as it stated that "member states, in accordance with the precautionary principle, shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs" (European Council 2001). Similarly, gaining public trust was the cornerstone emphasis of the agricultural biotechnology regulatory guideline

report published by the Australian Department of Agriculture, Fisheries and Forestry. According to the report, "four strategic imperatives are identified: a national path to market for biotechnology products and services; necessity to build consumer knowledge of biotechnology sciences and their applications (risks and benefits) and also consumer confidence in regulation; a refocus of the current regulation of genetic modification from an input-based process to an output-based process to ensure consistency across emerging technologies; and an engagement in international biotechnology science and research" (Staffas *et al.* 2013, pp. 2768).

Conclusion

Derived from a multi-jurisdiction, multi-sector review of regulation, the Penn programme identified three core areas or 'pillars' of regulatory excellence: stellar competence, empathic engagement and utmost integrity. As set out above, achieving each of these goals relates to the capabilities and competences of individual regulators, of the regulator as an organisation, and the broad systemic capabilities of regulation related to public value, legitimacy and trust.

Opinion on the excellence and effectiveness of existing regulation and regulatory efforts in the agri-food biotechnology sector has raised many concerns including "inattention to food safety, insufficient accountability to citizens via product labelling, threats to biodiversity and the environment, placing scientific progress ahead of the public interest and enhancing the power of large global corporations vis-à-vis poorer countries and consumers" (Laycock and Howlett 2013, p 5).

While enhancing the first two capacities set out above can address many of these concerns and can be relatively easily achieved through the dedication of additional resources to recruitment and training of qualified staff, and the provision of adequate informational and other resources to regulatory agencies, ultimately, the legitimation capacity of the political-administrative system must also be high in order to garner social and political trust on the part of stakeholders and the public (Wu *et al.* 2015; Woo *et al.* 2015).

Gaining public legitimacy has been a particular concern of regulators in the agri-food biotechnology sector and enhancing the legitimacy and public trust in regulators of new and future agricultural biotechnologies has been the subject of many efforts in this area. However, it is the most

difficult the three Penn indicators of regulatory excellence to achieve. That is, from the 'first generation' experience with GMOs, this issue continues to remain critical to effective regulation of 'second' and 'third' generation agricultural biotechnologies and efforts to bolster this capacity on the part of governments and regulators continue to remain a crucial barrier to achieving regulatory excellence in this sector.

References

Ansell, C. and A. Gash. 2007. "Collaborative Governance in Theory and Practice." *Journal of Public Administration Research and Theory,* 18, 543-571.

Belson, N.A. 2000. "US Regulation of Agricultural Biotechnology: An Overview." *AgBioForum*, *3*(4), 268-280

Coglianese, C. 2015. *Listening, Learning, Leading: A Framework for Regulatory Excellence.* Penn Programme on Regulation. University of Pennsylvania Law School.

Coglianese, C. and J. Nash. (eds.). 2006. *Leveraging the Private Sector*. Washington,

D.C.: Resources for the Future Press.

Dunlop, C. A. 2015. "Organizational Political Capacity as Learning." *Policy and Society*, 34(3), 259-270.

European Commission. 2000. *Communication from the Commission on the Precautionary Principle*, COM (2000) 1 Final (Brussels, 2 February).

European Council. 2001. *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMOs and repealing Council Directive 90/220/EEC*, OJ L 106, 17.4.2001.

Finkel, Adam M., D. Walters, and A. Corbett. 2015. "Planning for Excellence: Insights from an International Review of Regulators' Strategic Plans." Faculty Scholarship Paper 1567. Available at: http://scholarship.law.upenn.edu/faculty_scholarship/1567

Gardner, Nora, Kate Kolsky and Matt Smith. (2013). "Revolutionary Regulators," in *McKinsey Center for Government, Regulatory Excellence: Achieving Public Health Impact through Distinctive Regulatory Management Systems.* McKinsey and Company.

Gleeson, D., D. Legge D, D. O'Neill, and M. Pfeffer. 2011. "Negotiating Tensions in Developing Organizational Policy Capacity: Comparative Lessons to be Drawn." *Journal of Comparative Policy Analysis: Research and Practice,* 13, 237–263.

Graham, J. 2005. "Smart Regulation: Will the Government's Strategy Work?" *Canadian Medical Association Journal*, 173, 1469-1470.

Hood, C. 1995. "The 'New Public Management' in the 1980s: Variations on a Theme." *Accounting, Organizations and Society*, 20, 93-109.

Howlett, M., and D. Laycock. (eds.). 2013. *Regulating Next Generation Agri-Food Bio-Technologies*. Routledge.

Howlett, M., and Ramesh, M. 2015. "Achilles' Heels of Governance: Critical Capacity Deficits and their Role in Governance Failures." *Regulation & Governance*.

Hutter, B. M. 1997. *Compliance: Regulation and environment*. Oxford: Oxford University Press.

Komen, J., and G. Persley. 1993. *Agricultural Biotechnology in Developing Countries: A Cross-Country Review*. International Service for National Agricultural Research (ISNAR)

Johansson, A. 2013. "Pragmatism Revisited: An Overview of the Development of Regulatory Regimes of GMOs in the European Union" in M. Howlett and D. Laycock (eds.) *Regulating Next Generation Agri-Food Bio-Technologies*. Routledge.

Laycock, D., and M. Howlett. 2013. "Regulating Next Generation Biotechnologies" in M. Howlett and D. Laycock (eds.). *Regulating Next Generation Agri-Food Bio-Technologies*. Routledge.

Levidow, L. 2007. "European Public Participation as Risk Governance: Enhancing Democratic Accountability for Agbiotech Policy?" *East Asian Science, Technology and Society*, 1(1), 19-51.

Moynihan, D. P. 2008. *The Dynamics of Performance Management: Constructing Information and Reform*. Washington, D.C.: Georgetown University Press.

Pal, L. A., and I.D. Clark. 2015. "Making Reform Stick: Political Acumen as an Element of Political Capacity for Policy Change and Innovation". *Policy and Society*, 34(3), 247-257.

Radin, B. A. 2009. "What Can We Expect from Performance Measurement Activities?" *Journal of Policy Analysis and Management*, 28, 505-516.

Rotberg, R.I. 2014. "Good Governance Means Performance and Results." *Governance* 27(3), 511–518. doi: 10.1111/gove.12084.

Staffas, L., M. Gustavsson, and K. McCormick. 2013. "Strategies and Policies for the Bioeconomy and Bio-Based Economy: An Analysis of Official National Approaches." *Sustainability*, *5*(6), 2751-2769. Available at: http://www.mdpi.com/2071-1050/5/6/2751/htm

Tiberghien, Yves. 2012. "The global battle over the governance of agricultural biotechnology: the roles of Japan, Korea, and China" in Michael Howlett and David Laycock (eds.) *Regulating Next Generation Agri-Food Biotechnologies: Lessons from European, North American and Asian Experiences*. London: Routledge (series: Genetics and Society), Pp. 111-125.

Tiernan, A., and J. Wanna. 2006. "Competence, Capacity, Capability: Towards Conceptual Clarity in the Discourse of Declining Policy Skills." Paper presented at the Govnet International Conference, Australian National University, Canberra, Australia.

UK Environment Agency. 2013. "Regulating for People, the Environment and Growth." Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/312703/LIT_9902.pdf

Woo, J. J., M. Ramesh, and M. Howlett. 2015. "Legitimation Capacity: System-level Resources and Political Skills in Public Policy." *Policy and Society*, *34*(3), 271-283.

World Bank. 2006. *Handbook for Evaluating Infrastructure Regulatory Systems.* The World Bank, Washington, DC.

Wu, X., M. Ramesh, and M. Howlett. (2015). Policy capacity: A conceptual framework for understanding policy competences and capabilities. *Policy and Society,* 34(3–4): 165–171.